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DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Part 92

[Docket No. APHIS-2007-0158]

RIN 0579-AD30

Information from Foreign Regions Applying for Recognition of Animal Health Status

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: We are amending the regulations that govern the importation of animals and animal products by consolidating the list of factors APHIS considers when evaluating the animal health status of a foreign region and by setting out new factors APHIS will consider when evaluating a region as historically free of a specific disease. These changes will make clearer the types of information APHIS needs from a requesting region in order to conduct an evaluation.

EFFECTIVE DATE: [Insert date 30 days after date of publication in the Federal Register].

FOR FURTHER INFORMATION CONTACT: Dr. Kelly Rhodes, Regionalization Evaluation Services, Sanitary Trade Issues Team, National Center for Import and Export, VS, APHIS, 4700 River Road Unit 38, Riverdale, MD 20737-1231; (301) 851-3300.

SUPPLEMENTARY INFORMATION:

Background

The regulations in 9 CFR part 92, “Importation of Animals and Animal Products; Procedures for Requesting Recognition of Regions” (referred to below as the regulations), set forth the process by which a foreign government may request recognition of the animal health status of a region.

Section 92.2 of the regulations requires that such requests be accompanied by information regarding the region that will enable the Animal and Plant Health Inspection Service (APHIS) of the U.S. Department of Agriculture to evaluate the request.

On December 28, 2011, we published in the Federal Register (76 FR 81404-81408, Docket No. APHIS-2007-0158) a proposal¹ to amend the regulations by consolidating the 11 factors listed in § 92.2(b) that APHIS considers when evaluating the animal health status of a foreign region into 8 factors. We also proposed to establish criteria for recognizing a region as historically free of a specific disease. Our intent was to make clearer the types of information APHIS needs from a requesting region to conduct an evaluation. Additionally, although our regulations focus on requests from foreign regions, we noted that APHIS could initiate an evaluation of the disease status of a foreign region and, if we did, would conduct the evaluation using these same factors. We also proposed to remove a statement in § 92.2(d) that supporting information submitted with country requests will be made available to the public prior to initiation of rulemaking. We proposed to replace it with a statement that a list of regions that have requested recognition of their animal health status will be available to the public, and to leave in place a statement in § 92.2(f) that when APHIS makes its evaluation available for public

¹ To view the proposed rule and the comments we received, go to <http://www.regulations.gov/#!docketDetail;D=APHIS-2007-0158>.

comment, the public will have access to the information upon which APHIS based its evaluation, as well as the evaluation itself.

We solicited comments concerning our proposal for 60 days ending February 27, 2012. We received 12 comments (including two from the same person) by that date. They were from an organization representing pork producers, an organization representing cattle farmers and ranchers, an organization representing U.S. consumers, a wildlife conservation society, a State board of animal health, foreign governments, and individuals.

Six commenters supported the proposed changes.

Three commenters objected to the proposed rule. Two of the three said that they oppose the concept of regionalization for animal health status. Two also said they were concerned about APHIS' ability to predict outbreaks or detect disease threats under the current 11 factors and oppose finalizing a rule predicated on those factors. They cited several instances where regions APHIS had recognized as free of a disease had subsequently experienced an outbreak of that disease. One commenter also said that APHIS should not adopt international criteria for evaluating a region as historically free of a disease until we have conducted a scientific study to determine whether such recommendations are, in fact, capable of adequately assessing whether a country is historically free of a disease.

We are making no changes to the proposed rule in response to these comments.

Regionalization is an important principle of the World Trade Organization Agreement on the Application of Sanitary and Phytosanitary Measures (WTO-SPS Agreement). Regionalization is based on recognition that pest and disease conditions may vary across a country as a result of ecological, environmental, and epidemiological factors, and on the premise that these differences should be taken into account in developing science-based regulatory measures. The United

States has successfully applied the concept for decades in domestic disease control and eradication programs, and regionalization of the United States for bluetongue and other diseases has facilitated exports.

Our evaluations of regions for animal health closely consider a broad range of factors widely accepted by the international community for assessing the disease risks associated with a region. As discussed above, we provide an opportunity for the public to view and comment on our evaluations and the information upon which they are based prior to making a final determination. Finding that a region is free of a disease based on such an evaluation does not guarantee, however, that the region will always remain free of that disease. Our evaluations enable us to determine whether a disease is present in a region at a given time, ensure that the region has safeguards in place to protect against introduction of the disease, and ensure that the region is capable of detecting and containing the disease should it be introduced despite these measures.

Two commenters did not speak for or against the specific changes, but raised other issues, as follows.

One expressed concern that the reason for the changes was to expedite the evaluations for animal health status. The commenter stated that this should not be done at the expense of preventing foreign animal disease introductions into the United States.

We agree and point out that we are not changing the way we conduct evaluations. Our goal is to expedite the process of a region supplying us with the necessary information to conduct an evaluation.

One commenter expressed concern that APHIS emphasizes geographic, or zonal, freedom from disease over other approaches to trade in animal products that effectively mitigate

disease risks. He mentioned compartmentalization and commodity-based trade as two alternatives. As examples of the latter, he cited the international standards for trade in fresh beef from regions that vaccinate for foot-and-mouth disease and the international standards for trade in milk and deboned beef from regions where the risk of bovine spongiform encephalopathy is neither negligible nor controlled. He stated that eradication of livestock diseases may not always be realistic or feasible, especially in places like Africa, where the means for achieving zone freedom (fences, for example) can conflict with wildlife preservation efforts (e.g., ensuring wildlife have space and freedom to roam).

We are making no changes to the proposed rule in response to this comment. While this rulemaking addresses factors we consider when assessing the disease status of a geographic area, APHIS' regulations also include commodity-based requirements that allow for the importation of a variety of products from regions not considered free of diseases of concern. These requirements are contained largely in 9 CFR part 94. Inquiries regarding these requirements or requests for approval of new requirements may be directed to the National Center for Import and Export: Telephone (301) 851-3300 or e-mail AskNCIE.Products@aphis.usda.gov.

Additionally, several of the commenters addressed specific provisions of the proposal.

One commenter objected to the proposal to allow APHIS to initiate an evaluation of a foreign country's disease status in the absence of a request from that foreign country, stating that multinational meat packers might lobby APHIS to conduct such evaluations in order to source meat and livestock.

We are making no changes to the proposed rule in response to this comment. If there is a U.S. market for meat or livestock from a foreign region but APHIS has not yet evaluated its disease risk, the foreign government of that region will likely request an evaluation because of

the value those exports would have for the foreign region. In any case, as stated in the proposed rule, APHIS anticipates that most evaluations will be done at the request of a foreign country. There may be instances, however, when it will be beneficial for APHIS to initiate an evaluation, and we reserve the right to do so. Even in such cases, we could not conduct the evaluation without the cooperation of the foreign government, which would need to supply information and allow access for any necessary site visits. As with any evaluation, there would be opportunity for the public to review and comment on the evaluation and proposed disease status.

One commenter objected to our proposal to remove the statement in § 92.2(d) that supporting information submitted with country requests will be made available to the public prior to initiation of rulemaking. The commenter stated withholding such information will severely limit APHIS' transparency. Another commenter expressed concern that this change would reduce the amount of time that supporting information regarding a country's disease status is available to the public.

We are making no change in response to these comments. The intent of this statement was to assure the public that they will have access to, and opportunity to comment on, the information upon which APHIS bases its evaluation, as well as the evaluation itself. As discussed in the proposed rule, this has been our practice, and it will continue to be our practice. Moreover, there will be no change in when we make the supporting information available. We will continue to make both the supporting information and the evaluation available when we announce our intention to recognize the animal health status of a region and open the public comment period. We were concerned that the statement we proposed to remove suggested that the supporting information might be made available sooner, perhaps at the time of the initial submission of the request, when the information may be incomplete or inadequate. Additionally,

this is not the only information APHIS relies upon to make its determination. In addition to information provided by the requesting country, we also gather information from literature, reports, and site visits and consider all of this in preparing our evaluation. We believe that the public should consider all of the information together, and that it could be confusing or misleading to release it in stages.

One commenter requested that, when we make available to the public a list of regions that have requested recognition of their animal health status, we include an indication of the animal species and diseases under evaluation with respect to each region. Another commenter recommended that we encourage foreign jurisdictions to specify the type of animal or product they wish to export and that we also make that information available to the public when we have it.

We agree with the suggestions. Paragraph § 92.2(d) in this final rule provides that APHIS will list on its Web site each region that has requested APHIS recognition of its animal health status, the disease(s) under evaluation, and, if the information is available, the animal(s) or product(s) the region wishes to export.

One commenter said that while the proposed changes would facilitate the work of foreign governments in submitting information, he remains concerned about the length of time it can take to complete assessments. The commenter referenced provisions in Annex C of the WTO-SPS Agreement that recommend that Members publish the standard processing period for evaluation requests or communicate the anticipated processing period to the applicant upon request.

We are making no changes to the proposed rule in response to this comment. Because the time required for each evaluation varies, estimates must be made on a case-by-case basis, which APHIS will communicate with the applicant upon request, consistent with Annex C.

One commenter asked what we mean by the wording “safely granted” in proposed § 92.2(e), which says: “If, after review and evaluation of the information submitted in accordance with paragraph (b) or (c) of this section, APHIS believes the request can be safely granted, APHIS will indicate its intent and make its evaluation available for public comment through a document published in the Federal Register.”

We mean that APHIS has determined that imports from the region would present a low risk of introducing a particular disease into the United States and may be safely imported.

A few commenters also made suggestions or raised issues not directly related to the changes we proposed, including expanding APHIS’ oversight of other animals, including rodents; data sharing among regulatory agencies; conducting post-mortem examinations of a representative sample of imported livestock to rule out “potential disease”; and the agreement between the European Commission and the United States on sanitary measures. Because these matters are outside the scope of this rulemaking, we are not addressing them here.

Therefore, for the reasons given in the proposed rule and in this document, we are adopting the proposed rule as a final rule, with the change discussed above.

Executive Order 12866 and Regulatory Flexibility Act

This final rule has been determined to be not significant for the purposes of Executive Order 12866 and, therefore, has not been reviewed by the Office of Management and Budget.

In accordance with the Regulatory Flexibility Act, we have analyzed the potential economic effects of this action on small entities. The analysis is summarized below. Copies of

the full analysis are available on the Regulations.gov Web site (see footnote 1 in this document for a link to Regulations.gov) or by contacting the person listed under FOR FURTHER INFORMATION CONTACT.

The economic analysis identifies importers and producers of animals and animal products as the small entities most likely to be affected by this action and considers the reduction in time between receipt of a request by APHIS and initiation of an evaluation.

Based on the information presented in the analysis, we expect that decreasing the amount of time and APHIS resources required to conduct such an evaluation would not have a significant economic effect on the entities affected.

Under these circumstances, the Administrator of the Animal and Plant Health Inspection Service has determined that this action will not have a significant economic impact on a substantial number of small entities.

Executive Order 12988

This final rule has been reviewed under Executive Order 12988, Civil Justice Reform. This rule: (1) Preempts all State and local laws and regulations that are inconsistent with this rule; (2) has no retroactive effect; and (3) does not require administrative proceedings before parties may file suit in court challenging this rule.

Paperwork Reduction Act

This final rule contains no new information collection or recordkeeping requirements under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.).

List of Subjects in 9 CFR Part 92

Animal diseases, Imports, Livestock, Poultry and poultry products, Region, Reporting and recordkeeping requirements.

Accordingly, we are amending 9 CFR part 92 as follows:

PART 92--IMPORTATION OF ANIMALS AND ANIMAL PRODUCTS; PROCEDURES
FOR REQUESTING RECOGNITION OF REGIONS

1. The authority citation for part 92 continues to read as follows:

Authority: 7 U.S.C. 1622 and 8301-8317; 21 U.S.C. 136 and 136a; 31 U.S.C. 9701;
7 CFR 2.22, 2.80, and 371.4.

2. In § 92.2, paragraphs (a) through (f) are revised to read as follows:

§ 92.2 Application for recognition of the animal health status of a region.

(a) The representative of the national government(s) of any country or countries who has the authority to make such a request may request that APHIS recognize the animal health status of a region.¹ Such requests must be made in English and must be sent to the Administrator, c/o National Center for Import and Export, VS, APHIS, 4700 River Road Unit 38, Riverdale, MD 20737-1231. (Where possible, include a copy of the request and accompanying information in electronic format.)

(b) Requests for recognition of the animal health status of a region, other than requests submitted in accordance with paragraph (c) of this section, must include, in English, the following information about the region. More detailed information regarding the specific types of information that will enable APHIS to most expeditiously conduct an evaluation of the request is available at http://www.aphis.usda.gov/import_export/animals/reg_request.shtml or by contacting the Director, Sanitary Trade Issues Team, National Center for Import and Export, VS, APHIS, 4700 River Road Unit 38, Riverdale, MD 20737.

(1) Scope of the evaluation being requested.

¹ Additionally, APHIS may choose to initiate an evaluation of the animal health status of a foreign region on its own initiative. In such cases, APHIS will follow the same evaluation and notification procedures set forth in this section.

- (2) Veterinary control and oversight.
- (3) Disease history and vaccination practices.
- (4) Livestock demographics and traceability.
- (5) Epidemiological separation from potential sources of infection.
- (6) Surveillance.
- (7) Diagnostic laboratory capabilities.
- (8) Emergency preparedness and response.

(c) Requests for recognition that a region is historically free of a disease based on the amount of time that has elapsed since the disease last occurred in a region, if it has ever occurred, must include, in English, the following information about the region. More detailed information regarding the specific types of information that will enable APHIS to most expeditiously conduct an evaluation of the request is available at

http://www.aphis.usda.gov/import_export/animals/reg_request.shtml or by contacting the Director, Sanitary Trade Issues Team, National Center for Import and Export, VS, APHIS, 4700 River Road Unit 38, Riverdale, MD 20737. For a region to be considered historically free of a disease, the disease must not have been reported in domestic livestock for at least the past 25 years and must not have been reported in wildlife for at least the past 10 years.

- (1) Scope of the evaluation being requested.
- (2) Veterinary control and oversight.
- (3) Disease history and vaccination practices
- (4) Disease notification.
- (5) Disease detection.
- (6) Barriers to disease introduction.

(d) A list of those regions that have requested APHIS' recognition of their animal health status, the disease(s) under evaluation, and, if available, the animal(s) or product(s) the region wishes to export, is available at http://www.aphis.usda.gov/import_export/animals/reg_request.shtml.

(e) If, after review and evaluation of the information submitted in accordance with paragraph (b) or (c) of this section, APHIS believes the request can be safely granted, APHIS will indicate its intent and make its evaluation available for public comment through a document published in the Federal Register.

(f) APHIS will provide a period of time during which the public may comment on its evaluation. During the comment period, the public will have access to the information upon which APHIS based its evaluation, as well as the evaluation itself. Once APHIS has reviewed all comments received, it will make a final determination regarding the request and will publish that determination in the Federal Register.

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Done in Washington, DC, this 23rd day of July 2012.

Kevin Shea,

Acting Administrator, Animal and Plant Health Inspection Service.

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